Appln. No.: 10/080,791

Response Dated October 12, 2006

Reply to Office Communication of July 13, 2006

## **Remarks:**

The Office Communication of July 13, 2006 ("the Communication") states that applicants' Amendment of April 21, 2006 is not fully responsive to the Office Action of June 27, 2005 ("the Office Action") because the claimed apparatus of claim 21 has not been compared to the prior art used in the last rejection, and it has not been specifically pointed out exactly what **structure** is in the claims which is not in the prior art structure.

Applicants believe their prior Amendment to be fully responsive to the prior Office Action by mooting the rejections based upon the prior art through the incorporation of limitations found in claims the Office Action stated were allowable. Nonetheless, the following additional remarks are offered to advance the prosecution of this application. Applicants have also included their claims as presented with their reply of April 21, 2006.

## Means Plus Function Language of Claim 21 under 35 U.S.C. § 112, ¶ 6.

Applicants respectfully submit that the Communication misinterprets the claim amendments supplied with applicants' previous Amendment because it refers to "incorporating the anchoring means and then adding functional language as to its intended use." To the contrary, there is no "intended use" recited in applicants' claim 21, but rather limitations expressed in means plus function format. With respect to applicants' second introducer, claim 21 recites:

a second introducer loaded with a second endoluminal device having a proximal end and a distal end adapted to engage the first endoluminal device proximal end, the second introducer *comprising means* 

for anchoring the proximal end of the second endoluminal device while deploying the second endoluminal device sequentially from the proximal end to the distal end and

for releasing the proximal end of the second endoluminal device after deployment thereof prior to or concurrently with the removal of the second introducer, the second introducer further comprising an anterograde sheath mounted over the second endoluminal device and attached distally to a distal tip attached to a shaft extending axially through the second endoluminal device, the shaft distally movable for advancing the anterograde sheath to unsheathe the second endoluminal device.

The emphasized (italicized, bold) and set apart text highlights how applicants' claim properly employs two means plus function limitations permissible under 35 U.S.C. § 112, ¶ 6 to recite their structure. See Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 1318 (Fed. Cir. 1999)

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("Although use of the phrase 'means for' (or 'step for') is not the only way to invoke § 112, ¶ 6, that terminology typically invokes § 112, ¶ 6 while other formulations generally do not."). Accordingly, both applicants' means plus function limitations should be accorded patentable weight for purposes of comparison with the prior art. Specifically, the structure of applicants' invention, as claimed in claim 21, is configured to anchor "the proximal end of the second endoluminal device while deploying the second endoluminal device sequentially from the proximal end to the distal end" and to release "the proximal end of the second endoluminal device after deployment thereof prior to or concurrently with the remove of the second introducer...."

## Contrasting Applicants' Claim 21 to the Office Action's Proposed Prior Art

The Office Action does not specifically articulate a rejection of applicants' claim 21. To advance the prosecution of this application, however, applicants offer the following distinctions.

As the Office Action notes, Fiedler appears to teach a structure capable of reverse deploying an expandable stent. Fiedler, Fig. 4. Fiedler teaches a device that utilizes a sliding sleeve 60 over primary catheter tube 22 which can be hydraulically powered to slide the sleeve forward (distally) and reveal the proximal end of the expandable stent. Fiedler does not, however, teach or suggest applicants' means for anchoring and for releasing prior to or concurrently with the removal of the second introducer. Neither Fiedler's Fig. 4 nor its accompanying text describe any structure to perform these functions. Further, Fiedler's catheter tube is fixed and therefore does not teach or suggest applicants' movable shaft as recited in the last limitation of claim 21: "the shaft distally movable for advancing the anterograde sheath to unsheathe the second endoluminal device."

Likewise, Burton teaches a delivery device for a self-expanding stent. Like Fiedler, Burton lacks applicants' claimed means for anchoring and for releasing prior to or concurrently with the removal of the second introducer. While Burton does disclose a location balloon 14, this balloon is "to facilitate correct positioning" (Burton, col. 4 lines 25-41) rather than for anchoring or releasing the delivered stent. The location balloon disclosed by Burton is incapable of performing the anchoring and releasing function recited by applicants' claim 21 because the location balloon is positioned proximal to Burton's stent device in order to fix the balloon outside the urethra and the stent device inside the urethra. See Burton, Fig. 2.

Finally, Lazarus teaches an intraluminal grafting system including a graft having a plurality of staples for engaging the interior surface of the treated lumen. Lazarus teaches inflatable membrane 30 that is used in delivery and fixing the staples into the lumen by exerting an outward radial force. Lazarus, col. 6, lines 25-46. The inflatable membrane of Lazarus, however, is incapable of anchoring the proximal end of its endoluminal device because of its position proximal to the distal end of the graft. That is, the inflatable membrane cannot be used until the graft has already been deployed. Therefore, Lazarus also fails to teach applicants' means for anchoring and releasing the proximal end of a stent during reverse deployment.

For the foregoing reasons, applicants believe amended claim 21, and claims 22-30 depending directly or indirectly therefrom, are distinguishable over the prior art of record.

## Conclusion

Applicants believe the pending application to be in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,

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